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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,310	07/17/2003	Janice North	273012013101	4352
25225	7590	03/25/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,310

Applicant(s)

NORTH ET AL.

Examiner

Ray Henley

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/15/03</u> . | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment filed July 17, 2003 and Information Disclosure Statement and Rule 1.131 declaration filed December 15, 2003 have been received, entered into the application and considered by the Examiner. Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copies of form PTO-1449 (2 pages), the cited references have been considered.

Request

Applicants are requested to inform the Examiner should the present application become subject to an assignment agreement. In particular, it is noted that the parent application, i.e., Serial No. 10/199,662, is assigned to QLT, Inc., the same assignee as the application, i.e., 10/081,010, which forms the basis of U.S. Patent Application Publication No. 2003/0083649.

Claim Rejection - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1614

Claim 1, and thus its dependents are considered indefinite because it is incomplete in not particularly pointing out a treatment objective to be accomplished in a subject afflicted with macular edema.

Applicants may wish to amend claim 1 by inserting ---macular edema--- at line 1 of claim 1 after "treat" in order to overcome the present ground of rejection.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Margaron et al., (U.S. Patent Application Publication No. 2003/0083649) who teach a method of treating a patient suffering from macular edema which comprises irradiating said subject's macula with light having a wavelength absorbed by a photosensitizer, which may be green porphyrin or verteporfin, that is administered locally or systemically to the subject who may be a human. See page 1, col. 2, section [0010]; page 2, col. 1, section [0012], line 8 thereof, section [0013], lines 5 and 11 thereof; and section [0014]; page 3, col. 2, section [0034], especially line 8 thereof. The source of irradiation may be a laser (page 16, section [0150], line 1) and the light may be administered in a dosage not exceeding 100 J/cm² (page 2, col. 2, line 4 thereof) and which may be in a range of from 1 J/cm² to 50 J/cm², which would include a range of from 5 J/cm² to 30 J/cm² (see page 12, section [0099]).

Art Unit: 1614

Applicants' submission of the declaration under rule 37 CFR 1.131 has been considered in this matter, however, does not diminish the propriety of the rejection. In particular, the effective date of U.S. Patent Application Publication No. 2003/0083649 is the date of provisional application No. 60/269,599 filed February 15, 2001 while in the above mention declaration, a date of "prior to March 15, 2001" has been set forth. This showing does not establish a date prior to February 15, 2001 because "prior to March 15, 2001" includes dates of from February 16, 2001 up to March 15, 2001.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margaron et al., (U.S. Patent Application Publication No. 2003/0083649), as above.

Art Unit: 1614

The difference between the above and the claimed subject matter lies in that the reference does not teach that both eyes are treated; that visual acuity is increased; and the irradiation procedure of claims 2-4.

However, to the skilled artisan, the claimed subject matter would have been obvious because the reference teaches the reduction of inflammation (page 2, section [0010]) which would have improved visual acuity of a patient having inflamed ocular tissues. Also, it would have been readily obvious to treat both eyes of a subject should that subject be in need of treatment for both eyes. Also, the determination of the optimum irradiation procedure (as in present claims 2-4) to employ would appear to be a matter that would have been well within the purview of the skilled artisan.

Double Patenting

Obviousness-type Non-Provisional

Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,599,891. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to "macular edema" in general and thus would have encompassed the specific types of macular edema in patented claim 1. Also, the determination of the optimum irradiation procedure (as in present claims 2-4) to employ would appear to be a matter that would have been well within the purview of the skilled artisan.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Art Unit: 1614

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

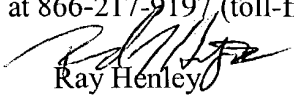
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Ray Henley
Primary Examiner
Art Unit 1614

Mar. 17, 2004